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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,953	09/17/2001	Junzo Sunamoto	Yanagihara Case 62	4435

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/22/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/936,953

Applicant(s)

SUNAMOTO ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1, 4-5, 7-9 are pending. The Amendment filed 6/12/03, Paper No. 5, amended claims 1, 4-5, 7 and 9, and cancelled claims 2-3 and 6.

Applicant's Amendment to the claims is sufficient-in-part to overcome the 35 USC 102 rejections in the previous Office Action and is sufficient to overcome the 35 USC 112 rejections in the previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "pullulan-cholesterol derivative" in claims 1 and 7 is vague and indefinite, as the metes and bounds of these claims are unascertainable. Chemically, what is encompassed by the term, "derivative". Derivative encompasses an incredible number of chemical modifications, thus it is not clear what this term means in the instant claims. The specification does not define this phrase and one of ordinary skill in the art would not be apprised of its meaning.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 4-5, 7, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi et al. (EP 370810).

Yamaguchi et al. teach fatty emulsions stabilized by polysaccharide derivatives, wherein the hydroxyl groups of mono-saccharide units of the pullulan are substituted by formula (1) of the instant invention at a proportion of 0.5-5 per 100 sugar units. Exemplified is a composition comprising N-[2-cholesteryloxycarbonylamino)ethyl]carbamoylemethylated pullan, panasate, glycerin, and water. Exemplified is a composition comprising N-[2-cholesteryloxycarbonylamino)ethyl]carbamoylemethylated pullan, soybean oil, glycerin, and water. Exemplified is a composition comprising N-[2-cholesteryloxycarbonylamino)ethyl]carbamoylemethylated pullan, fish oil, glycerin, and water. Exemplified is a composition comprising N-[2-cholesteryloxycarbonylamino)ethyl]carbamoylemethylated pullan, perilla oil, glycerin, and water. Exemplified is a composition comprising N-[2-cholesteryloxycarbonylamino)ethyl]carbamoylemethylated pullan, alpha linolenic acid, glycerin, and water (cosmetic components). Thus, both Applicant and Yamaguchi et al. teach emulsions comprising 0.001-50% pullulan-cholesterol derivatives, wherein the hydroxyl groups of the monosaccharide units are substituted in a proportion of 0.5-5 groups per 100 monosaccharide units by a radical of formula (1). See page 3, line 50-pg. 7, line 40.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al. as applied to claims 1, 4-5, 7, 9 above, and further in view of Kondo et al. (JP408119829) and Force et al. (4,740,367) .

The instant invention is directed toward a cosmetic product comprising cosmetic components and a pullulan-cholesterol derivative, wherein the hydroxyl groups of monosaccharide units constituting the pullulan of the pullulan-cholesterol derivative are substituted, in a proportion of 0.01-20 groups per 100 monosaccharide units, by a radical represented by the formula (1).

Yamaguchi et al. is applied as discussed above. The reference lacks a skin care cosmetic form.

Kondo et al. teach skin care compositions comprising perilla oil. See abstract.

Force et al. teach soybean oil as providing skin softness in cosmetic compositions. See Col. 6, lines 41-46.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of Yamaguchi et al. as a skin care composition because Yamaguchi et al. exemplify compositions comprising soybean oil and perilla oil and Force et al. teach that soybean oil is known to provide skin softness in skin care compositions, and Kondo et al. teach that using perilla oil in skin care compositions is known.

Response to Arguments

Applicant argues, "In this reference, the pullulan and the cholesterol are bonded through a spacer having the structure of $-OCH_2CONHCH_2CH_2NH-R$, in which R is cholesterol. In

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contrast thereto, in the present invention the spacer for bonding the pullulan and cholesterol has the structure -OCONHR1NHCOO-R2 , in which R1 is a hydrocarbon group and R2 is a cholesteryl group. As such there is an unobvious structural difference between the compounds of EP 370810 and the compounds of the present invention". This argument is not persuasive. First, the Examiner respectfully points out that R in Yamaguchi et al. is a cholesteryloxycarbonyl group, which is a $\text{-C(O)-O-cholesterol}$ group. Second, the Examiner respectfully points out that based on the examples of Yamaguchi et al., the $\text{"-OCH}_2\text{"}$ group in the first described formula above is actually a $\text{"-CH}_2\text{O-}"$ group, which is the methoxy group of the pullulan. Thus, the spacers of the instant invention and Yamaguchi et al. are the same.

Applicant argues, "The fatty emulsions disclosed in the European Patent may use oils and fats, such as fish oils, alpha linolenic acid. . . which are unsuitable for cosmetic use. This indicates that the fatty emulsion is intended to be used in nutrient infusion to be administered to the body via a blood vessel". This argument is not persuasive. First, this argument is not commensurate in scope with the instant claims, as the instant claims are directed to a composition and not to a method of use. Second, the Examiner respectfully points out that the recitation "cosmetic" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Third, the Examiner

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respectfully points out that fish oils and alpha linolenic acids are common fatty ingredients in cosmetic compositions.

Applicant argues, "In contrast to the European Patent, the cosmetic product according to the present invention is not always in the form of a fatty emulsion and does not contain alpha-linolenic acid". This argument is not persuasive, as it is not commensurate in scope with the instant claims. The Examiner respectfully points out that the instant independent claims place no limitation on the form of the composition. Furthermore, the transitional term "comprising", is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). MPEP 2111.03. Thus, it does not matter that the instant invention is silent in regard to alpha-linolenic acid.

Applicant argues, "The Kondo et al. and Force et al. references have been cited by the Examiner as teaching the use of oils. . .the perilla oil in Kondo et al. is contained in an external medicine and not in a cosmetic composition. Moreover, there is no motivation to incorporate the soybean oil of Froce et al. and the perilla oil of Kondo et al. with the composition disclosed in the European Patent". This argument is not persuasive. First, the Examiner respectfully points out that the previous Office Action never attempted to teach adding the oils of Kondo or Force

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into the composition of the EP patent. Kondo and Force were merely relied upon to teach that these oils, which are constituents of the composition of the EP patent, are known for imparting cosmetic benefits to the skin. Second, the Examiner respectfully points out that the composition of Kondo et al. is a cosmetic, as it is applied to the skin to provide beautification.

Applicant argues that he has established unexpected results over the prior art. This argument is not persuasive, as Applicant has provided no data comparing the instant composition with that of the closest prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

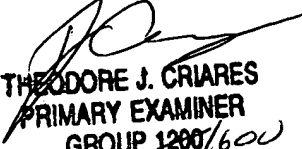
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
July 16, 2003


THEODORE J. CRIARES
PRIMARY EXAMINER
GROUP 1200/600